



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Los Angeles District 949221

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Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

December 1, 2003

W/L 11-04

Mr. Jaime Montiel
Gold Coast Produce
4444 Navalair Road
Oxnard, CA 93033

Dear Mr. Montiel:

The Food and Drug Administration (FDA) conducted an inspection of your facility located at 4444 Navalair Road, Oxnard, California on October 8, 10, and 20, 2003. At the conclusion of the inspection you were issued a Form FDA-483 (copy attached) which listed a number of insanitary conditions present in your firm at the time of that inspection. These conditions cause the products processed in your facility to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4), in that they were prepared, packed, or held under insanitary conditions whereby they may have become injurious to health.

You may find links to the FDA website at www.fda.gov.

The following is a list of the insanitary conditions observed by our investigators during the inspection (references are to current Good Manufacturing Practice regulations for human foods, Title 21, Code of Federal Regulations (21 CFR)).

1. Failure to provide employees with readily accessible and adequate toilet facilities.
[21 CFR 110.37(d)]

Specifically, the employee toilet facilities were observed to be inadequate. Your firm is utilizing two outdoor portable toilet facilities within approximately fifteen feet of the processing room's entrance door. There are two office toilet facilities which are used by neighboring businesses. These facilities are accessed by forty firm employees covering two shifts.

2. Failure to keep toilet facilities in good repair. [21 CFR 110.37 (d)(2)]

Specifically, on 10/10/03, both office toilet facilities were observed closed due to plumbing problems.

3. Failure to provide hand washing facilities at each location in the plant where needed. [21 CFR 110.37(e)(1)]

Specifically, the hand washing sink in the processing room was inaccessible. The hand washing sink is located along the wall behind the manufacturing line; employees have to duck under and around the lettuce manufacturing line to access it.

4. Hand washing facilities lack running water of a suitable temperature. [21 FR 110.37(e)]

Specifically, on 10//03 one of the two office toilet facilities in the main offic3e building lacked hot water. The hand washing sink outside of the outdoor portable toilet facilities has no hot water line and sufficient water pressure for effective hand washing.

5. Plumbing is not adequately installed and maintained to properly convey sewage and liquid disposable waste from the plant. [21 CFR 107.37(b)(2)]

Specifically, the hand washing sink located behind the lettuce processing line is inaccessible and was observed discharging wastewater directly onto the processing room's main drain where produce holding buckets are rinsed and the lettuce are being spun dried.

6. Failure to maintain equipment, containers, and utensils used to convey, hold, and store food in a manner that protects against contamination. [21 CFR 110.80(b)(7)]

Specifically,

- a. Your firm does not hold raw materials and ingredients in suitable containers so as to protect against contamination. White plastic buckets and containers utilized for temporary storage of processed vegetables and fruits were observed accumulated with debris cracked, broken and damaged.

- b. The three-layered white conveyor belt utilized for trimming lettuce was observed with dark stains and accumulation buildup; the pvc belt of this line, where the cut lettuce falls onto prior to being shredded, was observed covered with built-up accumulation and yellowish dark stains. The mechanical cutting blade unit of this line was also covered with sticky dark particle accumulation. On 10/8/03 the white conveyor belt in the lettuce trimming station was observed damaged, cracked and covered with slimy black built-up residue on the sides of the belt.
 - c. The white conveyor belt of the shorter-second processing line utilized for cutting vegetables was observed cracked, damaged, and covered with dark stains and accumulation build-up.
 - d. All cutting boards utilized for trimming and cutting fruits and vegetables were observed covered with deep cuts and grooves and black stains.
 - e. The plastic strips covering the two entrances to the neighboring cooler warehouses were damaged and covered with accumulation of what appears to be organic and inorganic matter. Forklifts drive through these plastic strips into the processing room. The packages of raw materials and finished products also come into direct contact with these strips.
7. Failure to clean utensils as frequently as necessary to protect against contamination of food. For example, your firm has no utensil or equipment washing sink or area. [21 CFR 110.35(d)]
8. Failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food and food-contact surfaces. [21 CFR 110.35(a)]

Specifically,

- a. A male employee was observed hosing down the plastic buckets while splashing water by the lettuce line and floor drain while other processing employees were packing and processing ready-to-eat foods within one foot of this area.
 - b. Your firm does not utilize hot water for washing equipment and utensils or mechanical washing operation.
9. Failure to properly maintain roads and yards so that they do not constitute a source of contamination in areas where food is exposed. [21 CFR 110.20(a)(2)]

Specifically, the ready-to-eat vegetable processing area is located between two raw material warehouse areas under the control of the owner of the building. The forklifts for the other firm routinely cross through the production area during food preparation

from the adjoining dirt road and warehouses. The floor in the processing area where the forklifts drive was covered with soil and tire tracks.

10. Proper precautions to protect food and food-contact surfaces from contamination with microorganisms, filth, and extraneous material cannot be taken because of deficiencies in plant construction and design. [21 CFR 110.20(b)(2)]

Specifically, boxes of raw materials as well as finished products are stored immediately adjacent to each other on pallets. Palletized boxes of green onion and oranges were observed stored along the boxes of finished products.

11. Failure to provide adequate screening or other protection against pests. [21 CFR 110.20(b)(7)]

Specifically, the entrance door to the processing room lacks a self-closing device and no additional barrier exists between the processing room and the exterior.

12. Failure to maintain physical facilities in repair sufficient to prevent food from becoming adulterated. [21 CFR 110.35(a)]

Specifically, the processing room floor was deteriorated and had standing puddles of water.

13. Failure to take necessary precautions to protect against contamination of food, food contact surfaces, and food packaging systems from microorganisms and foreign substances. [21 CFR 110.10(b)(9)]

Specifically, your firm does not have an effective measure to protect against the inclusion of metal and extraneous material in food.

The above violations are not meant to be an all-inclusive list of deficiencies in your facility. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with the Act.

You should take prompt action to correct the violations observed during FDA's most recent inspection. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

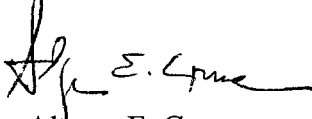
Please respond in writing within fifteen (15) days from your receipt of this letter. Your response should include each step that has been taken to completely correct the current violations and to prevent the recurrence of similar violations, the time within which correction will be completed, and any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, please explain the reason for your delay and the date by which each such item will be corrected and documented state when you will correct any remaining deviations.

Mr. Jaime Montiel, Gold Coast Produce

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Please send your reply to the Food and Drug Administration, Attention: Director, Compliance Branch, 19701 Fairchild Ave, Irvine, California 92612-2506. If you have any questions regarding any issue in this letter, please contact MaryLynn Datoc, Compliance Officer at telephone number 949-608-4428.

Sincerely,

A handwritten signature in black ink, appearing to read "Alonza E. Cruse". The signature is fluid and cursive, with a large initial "A" and a long horizontal stroke at the end.

Alonza E. Cruse
District Director

Cc: State Department of Public Health
Environmental Health Services
Attn: Chief Food and Drug Branch
601 North 7th Street, MS-357
P. O. Box 942732
Sacramento, CA 94234-7320